IPA Institute for Polyacrylate Absorbents

October 18, 2013

Dr. Ruth Lunn
Director, ORoC, DNTP
NIEHS
P.O. Box 12233
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Research Triangle Park, NC 27709

RE: Nominations to the Report on Carcinogens; Request for Information
Federal Register Vol. 78, No. 183, pp. 57868-57869 (September 20, 2013)

Dear Dr. Lunn:

I am writing on behalf of the Institute for Polyacrylate Absorbents (IPA) to respond to the NTP's request for information on polyacrylates, one of the substances nominated for possible review for future editions of the Report on Carcinogens (RoC). IPA, an affiliate of the Society of Chemical Manufacturers and Affiliates (SOCMA), is an industrial trade association that represents member companies which manufacture or handle polyacrylates for use in absorbent products. IPA's mission is to address, on a continuing basis, the scientific, regulatory and related issues which may impact health, safety and environmental aspects of the manufacture, use and disposal of fluid absorbing polyacrylates.

IPA is pleased to respond to NTP's request for information announced in the September 20, 2013 Federal Register notice. However, "polyacrylates" potentially covers a large range of substances and uses. Furthermore, polyacrylates were extensively studied in the 1990s and determined not to pose a risk of carcinogenicity or other significant health effects at levels to which humans are exposed. IPA is not aware of any more recent health effects studies that have changed that conclusion. Accordingly, so that IPA can prepare focused comments with pertinent information, we made a request to the Director of the Office of the Report on Carcinogens for either a copy of the nomination request or at least a summary of the basis for it (reference: email from Dr. C.T. Helmes to Dr. Ruth Lunn, September 26, 2013). To date, NTP has responded only with an explanation of the nomination process. IPA intends to pursue its request and reserves the opportunity to submit further comments once we receive further information.

As interim comments, IPA provides the following overview-level information about polyacrylates.

Polyacrylates have been used safely for decades in a variety of industrial and consumer products. Polyacrylate absorbents have improved personal care products such as disposable diapers, adult incontinence products, and feminine hygiene products. IPA understands that other uses of polyacrylates include cosmetics, thickening agents, elastic sealants, household products, cable wrap, horticultural and agricultural applications. As noted above, IPA's focus is polyacrylate absorbents used in personal care products.

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Two survey reports in the published literature describe in detail the extensive set of health effects studies relating to polyacrylates: the 1999 German MAK Commission Report, "Acrylic Acid, Polymer Neutralized, Cross-Linked," Vol. 15 *Occupational Toxicants*, Wiley-VCH (2001) (pp. 1-29 (available online at http://onlinelibrary.wiley.com/doi/10.1002/3527600418.mb900301nete0015/full); and a review by the Cosmetic Ingredient Review Expert Panel, Bergfeld, *et al.*, "Acrylate Copolymers," Final Report; Abstract (December 21, 1999), *International Journal of Toxicology*, 21 (Suppl. 3): 1-50, 2002 (available online at http://www.cir-safety.org/ingredient/acrylates-copolymer) (concluding that compounds in the Acrylate Copolymer group "are considered safe for use in cosmetic formulations when formulated to avoid irritation). As discussed in these reports, the toxicology of polyacrylates is well established. In summary, polyacrylates:

- have an acute oral and dermal toxicity in rats above 2,000 $mg.kg^{-1}$ body weight
- are not irritating to the skin of rabbits and humans
- may produce slight eye irritating effects, but these effects are due to mechanical processes
- are not skin sensitizers
- have no mutagenic or genotoxic potential
- have no effects on reproduction and are not teratogenic

The only noteworthy adverse effect associated with polyacrylate absorbents was identified following a chronic (2 year) rat inhalation study conducted at the Lovelace Inhalation Toxicology Research Institute and which was presented to US and European authorities in the 1990s. The effects were confined to the lungs at the higher exposure levels and were due to an inflammatory response resulting from impaired pulmonary clearance of the high molecular weight, low water soluble polyacrylate polymer. In that study, rats were exposed to an exclusively respirable fraction of polyacrylate dust (approximately 2 μm particle size).

By contrast, commercial granular polyacrylate absorbent polymers do not pose such an inhalation hazard as they are comprised of much larger particles, typically in the range of 300-700 μm. The proportion of particles <100 μm is limited to less than 1% in order to maintain the properties of the product. Therefore, commercially available polyacrylates contain practically no respirable dust.

Evaluating the 2-year inhalation study and other available toxicology data for water-absorbing polyacrylates, the German MAK Commission classified "polyacrylic acid, neutralized, cross-linked, in the form of respirable dust" (particle size < 10 μm) as Category 4 in its classification scheme: "substances with carcinogenic potential for which genotoxicity plays no or at most a minor role." Further, concluding that in the absence of a mutagenic or genotoxic response the observed response in the lung is attributed to poor solubility rather than inherent toxicity, the MAK Commission set an occupational exposure level – that for which "no significant contribution to human cancer risk is expected" – at the no observed effect level (NOEL) of 0.05 mg/m^3 (respirable dust) for the inflammatory response in the lung. MAK Commission Report (1999), *supra*.

The MAK Commission Report also reviewed the human epidemiology literature and concluded: "Epidemiological studies in the industries producing and processing cross-linked polyacrylates revealed no adverse effects on health and especially no lung changes or changes of lung function parameters." MAK Commission Report (1999), *supra*, at p. 2. Likewise, based on its review of the human clinical evidence, the Cosmetic Ingredient Review Expert Panel

stated: "[i]n clinical studies, Acrylate Copolymer and Sodium Polyacrylate did not produce irritation or sensitization. In examining the effects of workplace exposures, employees exposed to a variety of acrylic polymer dusts (as well as other materials) did not have an excess of chest x-ray abnormalities . . . ." *International Journal of Toxicology*, 21 (Suppl. 3) (2002), *supra*, at p. 44.

As part of its mission, IPA maintains an awareness of studies on the health effects of polyacrylates and acts on those studies accordingly. Since 1997, IPA member companies have produced and updated a workplace safe handling booklet and a 2013 edition was completed in collaboration with IPA's sister organizations in Europe and Asia, namely EDANA (the international association serving the nonwoven and related industries) and ASPIA (Asia Superabsorbent Polymers Industry Association). The booklet describes appropriate engineering and work practice controls, and respiratory protection to be used where such controls alone are not sufficient. IPA, EDANA, and ASPIA member companies voluntarily follow the occupational exposure guideline value of 0.05 mg/m^3 (respirable dust) recommended by the German MAK Commission in their operations that manufacture or handle polyacrylates.

As polyacrylates have been extensively studied and have been determined not to pose significant carcinogenic potential, IPA does not believe that polyacrylates warrant use of NTP's resources for further review or consideration. As noted above, we look forward to receiving information about the basis for the nomination so that we can address this issue with greater specificity.

Thank you for this opportunity to provide these initial comments. Please contact me directly at 202-721-4154 or at helmest@socma.com if you have any questions or for more information.

Sincerely,

[Redacted]

Dr. C. Tucker Helmes
Executive Director, IPA